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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,866	10/03/2006	Alexander A. Khromykh	252007	2237

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
02/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/577,866	KHROMYKH ET AL.	
	Examiner	Art Unit	
	AGNIESZKA BOESEN	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-22,25-39 and 41-64* is/are pending in the application.

4a) Of the above claim(s) *54-57 and 61-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-22,25-29,38,39,41-53 and 58-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2009 has been entered.

In the response to the election requirement on September 3, 2009 Applicant elected Group I, claims 51-53 and 58-60 and the species of praline residue 250. Claims 54-57 and 61-64 are withdrawn because they are drawn to non-elected invention. Claims 17-22, 25-29 and 38, 39, 41-53 and 58-60 are under examination in this Office Action

Claim Rejections - 35 USC § 112

Rejection of claims 17-23 and 26-29 under 35 U.S.C. 112, first paragraph, **is withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

Rejection of claims 17-22, 26, and 28 under 35 U.S.C. 102(e) as being anticipated by Westaway et al. (US Patent 6,893,866) **is withdrawn** in view of Applicant's amendment and arguments.

New Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-22, 25-29 and 38, 39, 41-53 and 58-60 are rejected under 35 U.S.C. 102(e) in alternative 102(a) as being anticipated by Khromykh (WO2003/046189 A1 in IDS on 10/3/2006).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Khromykh teaches methods of immunizing an animal comprising administering an isolated nucleic acid encoding an infectious attenuated Kunjin virus VLPs encoding and expressing a protein translation product comprising C protein, prM protein and E protein (see claims 51-62, Figures 10 and 11, Table 5, page 12, lines 24-29, page 14, lines 19-23, page 34, lines 19-25). The Kunjin virus VLP disclosed by Khromykh is in RNA form and encodes a heterologous nucleic acid encoding murine epitopes (see page 5, lines 25-30, page 10, lines 10-20, Figures 2, 3 and 11).

The flaviviral packaging system disclosed by Khromykh comprises mutations in nonstructural proteins: Leucine residue 250 substituted by Proline in the NS 1 nonstructural protein, (ii) Alanine 30 substituted by Proline in the nonstructural protein NS2A; (iii) Asparagine 101 substituted by Aspartate in the nonstructural protein NS2A; and (iv) Proline 270 substituted by Serine in the nonstructural protein NS5 (see claim 4, page 5, lines 1-15 and page 16, lines 1-10). Khromykh teaches CMV promoter and the IRESNeo selection marker (see page 9, lines 1-25, page 18, lines 10-15 and page 32, lines 30-31 and Figure 11). Khromykh teaches the BHK21 host cell (see page 18, lines 23-29, and Examples 1 and 4).

It is noted that the limitations "thereby eliciting a protective immune response to a West Nile Virus in the animal" and "thereby eliciting an immune response to at least another flavivirus in an animal" are not considered limiting because it express the intended result of the claimed method. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165,1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A whereby clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). See also Minton v. National Assoc. of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

The only active/positive method step recited in the present claims is administering an isolated nucleic acid encoding infectious attenuated Kunjin virus. Thus because Khromykh discloses the claimed method steps, Khromykh anticipates the present invention.

Thus by this disclosure Khromykh anticipates the present claims.

Claims 17, 18, 20-22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Khromykh et al. (Journal of Virology, 2001, Vol. 75, p. 4633-4640).

Khromykh discloses a method of vaccination/immunization using attenuated full-length DNA clones of Kunjin virus (see Materials and Methods and Discussion on page 4640, and Figure 1). Khromykh discloses the DNA nucleic acid operably linked to the promoter in BHK mammalian cell and the RNA nucleic acid (see page 4634). Khromykh discloses that the RNA is packaged in virions (see page 4634).

It is noted that the limitation "thereby eliciting a protective immune response to a West Nile Virus in the animal" is not considered limiting because it express the intended result of the claimed method. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165,1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A whereby clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). See also Minton v. National Assoc. of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

The only active/positive method step recited in the present claims is administering an isolated nucleic acid encoding infectious attenuated Kunjin virus. Thus because Khromykh discloses the claimed method steps, Khromykh anticipates the present invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17-22, 25-29, 38, 39, 41-53 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khromykh et al. (Journal of Virology, 2001, Vol. 75, p. 4633-4640) in view of Hall et al. (Virology, 1999, Vol. 264, p. 66-75).

Khromykh teaches a method of vaccination/immunization using attenuated full-length DNA clones of Kunjin virus (see Materials and Methods and Discussion on page 4640 and Figure 1). Khromykh discloses the DNA nucleic acid operably linked to the promoter in BHK mammalian cell and the RNA nucleic acid (see page 4634). Khromykh discloses that the RNA is packaged in virions (see page 4634).

It is noted that the limitations "thereby eliciting a protective immune response to a West Nile Virus in the animal" and "thereby eliciting an immune response to at least another flavivirus in an animal" are not considered limiting because they express the intended result of the claimed method. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165,1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A whereby clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). See also Minton v. National Assoc. of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

The only active/positive method step recited in the present claims is administering an isolated nucleic acid encoding infectious attenuated Kunjin virus. Because Khromykh discloses the claimed method step, Khromykh anticipates the present invention.

While Khromykh teaches an infectious attenuated Kunjin virus Khromykh does not teach any specific attenuating mutations comprised in the Kunjin virus. Khromykh does not expressly teach mammals, humans, equine or avian subjects. Khromykh does not teach an attenuating mutation in the proline residue 250 of the Kunjin virus non-structural protein NS1. Khromykh does not teach a substitution mutation of proline residue 250 by leucine, valine, or alanine.

Hall teaches attenuated Kunjin virus comprising a substitution mutation at proline residue 250 of the in non-structural protein NS1 (see the entire document).

It would have been *prima facie* obvious and one would have been motivated to provide the method taught by Khromykh and to administer an attenuated full-length DNA clone of Kunjin virus comprising Hall's substitution mutation at proline residue 250 of the in non-structural protein NS1 to mammals, humans, equine or avian subjects because Hall teaches that the mutation at proline residue 250 in non-structural protein NS1 results in delay in viral replication and reduction of virulence in mice however it still allows secretion of NS1 protein (see abstract, title and Results).

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

Rejection of claims 17-29 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-31 of copending Application No. 10/559,146 **is withdrawn** in view of Applicant's amendment.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Agnieszka Boesen/

Examiner, Art Unit 1648